

REMARKS

Claims 1-15 and 17-35 are currently pending. Claims 17-35 have been canceled. New claims 36-40 have been added. Support for new claim 36 can be found, for example, at col. 2, ll. 42-44. Support for new claims 37-38 can be found, for example, in Fig. 1. Support for new claim 39 can be found, for example, at col. 2, ll. 39-54. Support for new claim 40 can be found, for example, at col. 3, ll. 16-36.

I. Interview Summary

Applicants would like to thank the examiner for conducting a personal interview with Applicants' representatives on May 24, 2005. Claims 1-15 and the bases for their rejection were discussed. The substance of new claims 36-39 was also discussed. The rejections that were discussed during the interview are summarized in sections (VI) – (VIII) below.

II. Reissue Oath

As indicated on page 3 of the office action, a reissue declaration was not filed with the reissue application. Thus, applicants respectfully submit that a reissue declaration, not a supplemental declaration, is required. An executed reissue declaration will be filed shortly. If the examiner has not received the declaration in due time, a courtesy call to Applicants' undersigned representative, prior to the mailing of an office action, would be greatly appreciated.

III. Statement Under 37 CFR 3.73(b)

The office action indicates that the Statement filed under 3.73(b) was improperly dated. An executed Statement will be filed shortly.

IV. Objection to Claim Amendments

The office action indicates that the new claims added to the application must be underlined and that appropriate correction is required. However, this requirement, as applied to claims 17-35, is now moot in view of their cancellation.

V. Rejection Under 35 USC § 112, First Paragraph

Claims 17-35 have been rejected for lack of written description. Since these claims have been canceled, the rejection is now moot.

The office action objects to the recitation of “bacterial infection in a human or non-human animal” in claim 34. Applicants respectfully disagree. Nonetheless, to expedite prosecution, claim 34 has been re-presented as a new claim 40 without the objected-to recitation. Applicants expressly reserve their right to pursue any or all of the canceled claims, including claim 34, in a continuation application. Support for new claim 40 can be found, for example, at col. 3, ll. 16-36.

VI. Rejection Under 35 USC § 112, Second Paragraph

Claim 8 has been rejected as indefinite. The office action states that the preamble reads on making an ethanolate of azithromycin while the claim reads on isolating the crystals of azithromycin. Applicants respectfully disagree. Nonetheless, to expedite prosecution, claim 8 has been amended to better match the preamble with the rest of the claim. For instance, in the interview the examiner agreed the isolating step was an unnecessary limitation and has been deleted from the claim.

VII. Rejection Under 35 USC § 102(b)

Claim 23 has been rejected as anticipated by Bright (US 4,474,768). This rejection has been rendered moot by cancellation of this claim.

VIII. Rejection Under 35 USC §§ 102/103

All of the pending claims have been rejected under 35 USC § 102(a) as anticipated by or, in the alternative, under 35 USC § 103(a) as obvious over Bright. The office action states that the claimed ethanolate of azithromycin is inherently formed by Bright’s disclosed process. In addition, the office action states that any differences between the claimed compound and the inherently formed compound of Bright would be deemed to be minor and not patentably distinct. Applicants respectfully disagree.

Bright does not describe or suggest that the compound described in Example 3, or any other example, is a non-hygroscopic ethanolate of azithromycin containing about 1.5% to about

3% ethanol, as recited in the claims as currently amended. Moreover, Bright describes the crystallization of azithromycin by a process that is substantially different from the process of the claimed invention; indeed, Applicants' claimed process recites specific steps that are not disclosed in Bright.

In addition, there is substantial evidence that the compound formed in Example 3 of Bright is a hygroscopic azithromycin monohydrate, not the claimed non-hygroscopic ethanolate of azithromycin. Bright was filed in 1982 and assigned to Pfizer. EP 298,650 ("the '650 application") is a published application that claims priority to a PCT application filed in 1987, which is also assigned to Pfizer. The '650 application is directed to azithromycin dihydrate, which is stated by Pfizer to directly address the unstable, hygroscopic monohydrate form disclosed in its earlier Bright patent.

Specifically, the '650 application states that Example 3 of Bright "was obtained as hygroscopic monohydrate (for details see Preparation 1 below). Because of its hygroscopic nature, it is most difficult to prepare and maintain this prior monohydrate product in a form having a constant, reproducible water-content." P. 2, ll. 13-16. Preparation 1 reports an ethanol content of 1.09%. Thus, the extrinsic evidence indicates that none of the compounds disclosed in Bright inherently contains about 1.5% to about 3% ethanol, as recited in claim 1, for example, of the pending application.

Furthermore, nothing in Bright suggests that it was trying to obtain an ethanolate of azithromycin or that the inventors had any reason to believe that a non-hygroscopic ethanolate of azithromycin was obtainable. Thus, there is not a hint of motivation for one of skill in the art to modify Bright to even try to obtain a stable ethanolate of azithromycin, and the office action fails to identify any such motivation. The claimed invention is therefore not obvious in view of Bright.

The term "non-hygroscopic" is supported, for example, by the descriptions at col. 1, ll. 37-40, col. 2, ll. 23-31, and Fig. 1.

As indicated in the examiner's Interview Summary, these arguments were discussed and an agreement was reached that the claims, as currently amended, should be sufficient to overcome the rejections based on Bright.

IX. Conclusion

Entry of the foregoing amendments is respectfully requested. The Examiner is invited to contact the undersigned at 202-220-4200 to discuss any matter regarding this application.

No fee is believed due. However, the Office is authorized to charge any fees or credit any overpayment to Kenyon & Kenyon Deposit Account 11-0600.

Respectfully submitted,



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